IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AMGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 18-956 (MSG)
	)	
ACCORD HEALTHCARE, INC.,	)	
	)	
Defendant.	)	

AMGEN'S ANSWERING CLAIM CONSTRUCTION BRIEF

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Accord's opening claim construction brief is the latest example of its refusal to participate in this litigation while its summary judgment motion is pending. For example, Accord has refused to produce any witnesses for deposition before the Court rules on its summary judgment motion. *See* D.I. 27. Accord has also failed to produce any documents beyond its Abbreviated New Drug Application and correspondence with the FDA concerning the application. *See id.* Now, Accord contends in its opening claim construction brief that "this case is appropriate for early summary judgment of non-infringement" and that "formal claim construction proceedings are unnecessary." D.I. 68 at 1. This conduct flies in the face of the deadlines imposed by the Court's scheduling order, which expressly contemplates that the parties will proceed with discovery and claim construction proceedings while Accord's motion is pending. *See* D.I. 27.

Accord's opening brief fails to articulate any reasons why its proposed constructions should be adopted. Indeed, Accord does not cite a single piece of evidence—intrinsic or extrinsic—in support of either of its proposed constructions. Accord's sole argument in favor of its construction of claims 1 and 20 element (c) is that issue preclusion applies. But Accord failed to plead issue preclusion, and it makes no effort to demonstrate how the required elements are satisfied in this case. *See* D.I. 68 at 1-2. Similarly, Accord cites no evidence in support of its construction of "hydroxypropyl methylcellulose," offering only the conclusory statement that "there does not appear to be any basis for construing the term to mean anything other than simply 'hydroxypropyl methylcellulose.'" *Id*. at 2.

As discussed at length in Amgen's opening brief and below, Amgen's proposed constructions are supported by the intrinsic evidence, and the ordinary and customary meaning of the disputed claim terms as understood by a POSA. The fact that a summary judgment motion is

pending does not excuse Accord's failure to support its proposed claim constructions with evidence. As such, the Court should adopt Amgen's proposed constructions.

I. Claims 1 and 20 Element (c): "from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof"

Amgen's and Accord's proposed constructions of claims 1 and 20 element (c) differ in two primary respects: (1) Amgen's proposed construction allows for unlisted binders in the claimed pharmaceutical compositions (in addition to the required weight percentage of at least one of the listed binders) while Accord's does not; and (2) only Amgen's proposed construction recognizes that a person of ordinary skill in the art ("POSA") would have understood that the recited binders can all function as hardening binders in pharmaceutical formulations prepared using wet processing techniques, i.e., they are all binders "capable of forming liquid bridges that harden upon drying." Amgen's opening brief explains in detail why Amgen's proposed construction of element (c) is correct. Accord's opening brief, however, does not explain why Accord's proposed construction is correct and does not cite any intrinsic or extrinsic evidence in support of its construction. Instead, Accord's sole argument is that issue preclusion compels the Court to adopt its proposed construction. This is incorrect. Accord failed to meet its burden to plead and prove issue preclusion. And, in any event, the elements of issue preclusion are not satisfied here.

A. Accord Failed to Plead and Prove Issue Preclusion

"Collateral estoppel, or issue preclusion, is an affirmative defense," and "it is incumbent upon the defendant to plead and prove such a defense." *Taylor v. Sturgell*, 553 U.S. 880, 907 (2008). "[A] party asserting preclusion must carry the burden of establishing all necessary elements." *Id*. (quoting 18 Wright & Miller § 4405, at 83). Indeed, Accord acknowledges in its

opening brief that it bears the burden to prove issue preclusion. D.I. 68 at 2 ("The ***defendant must show*** [listing elements of issue preclusion]") (quoting *Comair Rotron Inc. v. Nippon Densan Corp.*, 49 F.3d 1535, 1537 (Fed. Cir. 1995)) (emphasis added). Thus, Accord was required to plead issue preclusion, and had the burden to prove that the required elements were satisfied.

Yet Accord neither pleaded nor proved issue preclusion. Accord's Answer and Counterclaims do not mention issue preclusion, collateral estoppel, or res judicata. *See* D.I. 10. Accord has had ample opportunity to plead issue preclusion, and has been aware of Amgen's claim construction positions since at least March 18, 2019, when Amgen served its infringement contentions. Moreover, even if Accord were permitted to argue issue preclusion, Accord has failed to meet its burden to prove that the elements of issue preclusion are satisfied. Accord does not explain how this Court's decision in *Amgen Inc. v. Amneal Pharmaceuticals, Inc. et al.*, No. 16-853 (MSG) (the "Previous Action) satisfies any of the elements of issue preclusion. Instead, Accord attempts to shift the burden of proof to Amgen, alleging that "Amgen cannot seriously dispute that each of [the] requirements [for issue preclusion] has been met." D.I. 68 at 2. This single sentence is clearly insufficient to meet Accord's burden and, consequently, Accord has failed to prove that issue preclusion applies.[1]

B. Issue Preclusion Does Not Apply

Issue preclusion applies only if all six of the following elements are satisfied: (1) the identical issue was previously decided; (2) the issue was actually litigated; (3) the previous determination was necessary to the decision; (4) the party being estopped was fully represented

[1] Although it is not Amgen's burden to disprove issue preclusion, Amgen explained in detail in its Opening Brief that issue preclusion does not apply for several reasons. *See* D.I. 69 at 11-14.

in the prior action; (5) the party being estopped had a full and fair opportunity to litigate the issue in the prior action; and (6) the issue was determined by a final and valid judgment. *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006). Here, Accord cannot prove at least elements (3), (5), and (6).

First, the claim construction rulings in the Previous Action are currently being considered on appeal and are therefore not final. *See* D.I. 69 at 11-12; *Phil-Insul Corp. v. Airlite Plastics Co.*, 854 F.3d 1344, 1357-58 (Fed. Cir. 2017). Because the claim construction rulings are not final, issue preclusion cannot apply.

Second, as Accord's cited cases make clear, Accord cannot show that the prior claim construction was necessary to any of the non-infringement judgments in the Previous Action. *See Comair Rotron Inc.*, 49 F.3d at 1539 (citing *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 704 (Fed. Cir. 1983)). To be sure, in the Previous Action, the Court construed element (c) as excluding unlisted binders from the claimed pharmaceutical compositions. However, the Court did not hold that any party's proposed generic product avoided infringement of the '405 patent based upon the inclusion of an unlisted binder. *See* Previous Action D.I 375, 376, 384. Thus, issue preclusion does not apply here. *See A.B. Dick Co.*, 713 F.2d at 704 ("Judicial statements regarding the scope of patent claims are entitled to collateral estoppel effect in a subsequent infringement suit only to the extent that determination of scope was essential to a final judgment on the question of validity or infringement," and "such statements should be narrowly construed").

Third, Amgen did not have a full and fair opportunity to litigate the construction of the binder limitation in the Previous Action. Having just inherited the prior litigation close to the eve of trial, the Court took up the construction of element (c) for the first time at the pretrial

conference without affording Amgen the opportunity to submit expert testimony on the issue, or brief its claim construction arguments in advance of a *Markman* hearing. *See* D.I. 69 at 12-14. Thus, Amgen did not have a full and fair opportunity procedurally, evidentially, and substantively to litigate its claim construction positions because it was not afforded an opportunity to present expert testimony or participate in full and appropriate *Markman* proceedings.

Fourth, equity dictates that Amgen should not be precluded from presenting its claim construction positions on element (c) in this case. "[N]o one set of facts, no one collection of words or phrases, will provide an automatic formula for proper rulings on estoppel pleas. In the end, the decision will necessarily rest on the trial courts' sense of justice and equity." *Blonder-Tongue*, 402 U.S. at 333–34. Because "claim construction often involves a fluid process," equity favors not precluding Amgen from rearguing the proper construction of the binder limitation. *See, e.g., Cadence Pharm., Inc. v. Innopharma Licensing LLC*, No. 14-1225-LPS, 2016 WL 3661751, at *3 (D. Del. Jul. 8, 2016); *see also Jack Guttman, Inc. v. KopyKake Enters., Inc.*, 302 F.3d 1352, 1361 (Fed. Cir. 2002) ("District courts may engage in a rolling claim construction, in which the court revisits and alters its interpretation of the claim terms as its understanding of the technology evolves."). Amgen submits that the Court should revisit its claim construction ruling in the Previous Action with the assistance of Dr. Williams' expert testimony regarding the technology at issue, the parties' briefs, and oral argument presented at the *Markman* hearing scheduled for August 19, 2019. *See* D.I. 69 at 14.

II. "hydroxypropyl methylcellulose"

Accord does not cite any intrinsic or extrinsic evidence in support of its proposed construction of "hydroxypropyl methylcellulose." Accord offers only the conclusory statement that "there does not appear to be any basis for construing the term to mean anything other than

simply 'hydroxypropyl methylcellulose.'" D.I. 68 at 2. To the contrary, Amgen's opening brief explains in detail—with citations to the intrinsic record and expert testimony—why construction is necessary and why its proposed construction ("any hydroxypropyl methylcellulose present in the composition") is correct. *See* D.I. 69 at 17-19. The Court should adopt Amgen's proposed construction for the reasons stated in Amgen's opening brief.

III. Any New Arguments Presented for the First Time in Accord's Answering Brief Would Be Untimely

Given the brevity of Accord's opening brief, Amgen anticipates that Accord may attempt to raise new arguments for the first time in its answering brief. But this Court's local rules prohibit reserving for a later brief any material that should have been included in a full and fair opening brief. *See* D. Del. L.R. 7.1.3(c). Indeed, such tactics "amount[] to impermissible 'sandbagging.'" *Rockwell Tech., LLC v. Spectra-Physics Lasers, Inc.*, 2002 WL 531555, at *3 (D. Del. March 26, 2002) (citing *Jordan v. Bellinger*, 2000 U.S. Dist. LEXIS 19233, at *18 (D. Del. April 28, 2000)). Consequently, new arguments presented for the first time in Accord's answering brief would be untimely and the Court should refuse to consider them. *See id.*

IV. Conclusion

Amgen respectfully requests that the Court adopt Amgen's proposed constructions of the disputed claim terms.

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July 19, 2019

CERTIFICATE OF SERVICE

I hereby certify that on July 19, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on July 19, 2019, upon the following in the manner indicated:

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